K123156

DEC 13 2012

5 510(k) SUMMARY [21 CFR 807.92(a)]

1. 510(k) Owner's Contact Information: name, address, phone and fax numbers, name of contact person, and date the summary was prepared [807.92(a)(1)]

Applicant: W. L. Gore & Associates, Inc.
32360 N. North Valley Parkway
Phoenix, AZ 85085

Contact: Sharon Alexander
Regulatory Affairs
Direct: (623) 234-5440
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Email: salexand@wlgore.com

Date Prepared: October 3, 2012

2. Name of the Device: including the trade or proprietary name, if applicable, the common or usual name, and the classification name, if known [807.92(a)(2)]

- Trade name: GORE® Flow Reversal System
- Common name: Occlusion catheter
- Classification name: Temporary carotid catheter for embolic capture
- Classification: 21 CFR 870.1250, NTE, Class II

3. Device Predicate [807.92(a)(3)]

K083300, GORE® Flow Reversal System

4. Description of the Device [807.92(a)(4)]

The GORE® Flow Reversal System consists of three primary components:

- GORE® Balloon Sheath
- GORE® Balloon Wire
- GORE® External Filter

When assembled together, the GORE® Flow Reversal System reverses the flow of blood at the treatment site of the internal carotid artery (ICA), directing embolic particles away from the neurovascular circulation and removing them through an external filter.

5. Intended Use [807.92(a)(4)]

The GORE® Flow Reversal System is intended to provide embolic protection during carotid artery angioplasty and stenting for the patients

diagnosed with carotid artery stenosis and who have the appropriate anatomy described below:

- Adequate iliac/femoral access
- Common carotid artery diameters between 6 and 12 mm
- External carotid artery diameters less than 6 mm

6. Summary of Similarities and Difference in Technological Characteristics, Performance and Intended Use:

   The modified GORE® Flow Reversal System is substantially equivalent to the currently marketed predicate device in its intended use, technological characteristics and performance.

7. Predicate Device Comparison [807.92(a)(6)]

   Non-clinical evaluations of the modified GORE® Flow Reversal System included biocompatibility testing in accordance with ISO 10993-1, sterilization, shelf life, and performance testing, including functional, mechanical and physical evaluations. The results of these tests demonstrate that the technological characteristics such as product performance, design, materials and the intended use are substantially equivalent to the currently marketed predicate device.

8. Conclusion

   The modified GORE® Flow Reversal System is substantially equivalent to the predicate GORE® Flow Reversal System (K083300) in terms of design, material composition, intended use and performance attributes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DEC 1 3 2012

W.L. Gore & Associates, Inc.
c/o Sharon Alexander, Regulatory Affairs Associate
Medical Products Division
32360 N North Valley Parkway
Phoenix, AZ 85085
United States

Re: K123156
Trade/Device: Gore Flow Reversal System Model
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: October 3, 2012
Received: November 13, 2012

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K123156

Device Name: GORE® Flow Reversal System

Indications for Use:

The GORE® Flow Reversal System is intended to provide embolic protection during carotid artery angioplasty and stenting for the patients diagnosed with carotid artery stenosis and who have the appropriate anatomy described below:

- Adequate iliac/femoral access
- Common carotid artery diameters between 6 and 12 mm
- External carotid artery diameters less than 6 mm

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K123156